REMARKS

With this amendment, claims 1-21 and 26-35 are pending in the application. Claims 1, 13, 26 and 34 are the only claims in independent form. Claims 22-25 have been cancelled as being directed to non-elected subject matter. Applicant reserves the right to pursue these claims in subsequent divisional filings. Claims 31-33 and 35 have been cancelled. New claims 36-46 have been added. Support for these claims is found in the specification, for example, at p. 31, lines 7-20 and Examples 15-17 and 23-25. Applicant submits that no new matter is added by way of these amendments.

Specification

Applicant respectfully requests entry of the information disclosure statement filed October 1, 2002. Consistent with MPEP 1893.03(g), the references cited in Form 1449 filed October 1, 2002 should not be provided as the same were received according to the notice of acceptance of application under 35 U.S.C. §371 and 37 CFR 1.494 mailed in this case June 12, 2002 and appended hereto. MPEP 1893.03(g) states in relevant part:

> The examiner will consider the documents cited in the international search report, without any further action by applicant under 37 CFR 1.97 and 1.98, when both the international search report and copies of the documents are indicated to be present in the national stage file. The examiner will note the consideration in the first Office action. There is no requirement that the examiners list the documents on a PTO-892 form.

As such, Applicant respectfully requests acknowledgement of the consideration of these references and the entry of Form 1449 submitted October 1, 2002 solely for the purpose of having such references printed on the cover page of any patent that may issue herefrom.

Priority

Applicant notes with appreciation the acknowledgement of the provisional application drawn to the same subject matter. Applicant submits the filing date of provisional application

60/094,096 from which priority is claimed herein has a filing date of July 24, 1998 and not July 23, 1998 as stated in Paper No. 16.

Remarks Directed Towards Objections

Claim 35 is objected to for improper dependency. Claim 35 has been cancelled and thus the objection is now moot.

Remarks Directed Towards Claim Rejections

Remarks Directed to Rejection under 35 U.S.C. §101

Claims 31-33 are rejected under 35 U.S.C. §101 as improper process claims. Claims 31-33 have been cancelled.

Remarks Directed to Rejection under 35 U.S.C. §102(b)

Claims 34 was held to lack novelty under 35 U.S.C. §102(b) as being anticipated by Chee et al., U.S. Patent 5,856,104.

In order for the cited reference to have anticipated Applicant's invention, the reference must teach every element of the claim. (MPEP, 7th Ed., revision 1, 2131) Independent claim 34 of the present invention teaches "reagents for identifying single nucleotide polymorphisms in a FcαRI genotype or phenotype together with instructions for the use thereof as a test to identify individual susceptibility to a disease."

Chee et al. is cited as teaching a "commercial package and/or a reagent kit, comprising reagents for the PCR based detection of polymorphisms and further teach the accompaniment of instructions for carrying out the methods." (paper 16, p. 3) However, in contrast to the present claims, Chee et al. does not appear to teach reagents for detecting polymorphisms in a FcαRI genotype or phenotype taught in the present invention. On the basis of these arguments it is submitted that claim 34 is not anticipated under 35 U.S.C.

§102(b) by Chee et al. Therefore, it is respectfully requested that the rejection of claim 34 as anticipated by Chee et al. be withdrawn.

Remarks Directed to Rejection under 35 U.S.C. §112, First Paragraph

Claims 1-21 and 26-35 stand rejected as not enabled by the specification because "the skilled artisan would be required to practice undue and unpredictable trial and error experimentation to practice the invention that is claimed." (paper 16, p. 8)

Specifically, the claims are cited as not enabled because "[t]he specification does not specify any examples of well-established, in vitro model systems or evidence for the ability of a cell's receptors (FcαRI) to bind IgA and its predictable association with cellular susceptibility to any disease." (paper 16, p. 4) However, it is well-established case law that:

> Compliance with the first paragraph of 35 U.S.C. 112 does not turn on whether a specific example or working example is disclosed. The specification need not contain a working example if the invention is otherwise disclosed in such a manner that one skilled in the art will be able to practice it without an undue amount of experimentation. *In re Borkowski*, 164 USPQ 642 (CCPA 1970).

In the present case, an inventive method as described by the claims is believed to be disclosed such that one of skill in the art can practice it without undue experimentation.

The steps of a method of claim 1 and dependent claims 2-12 include "identifying a FcαRI genotype of said cell." The identification of FcαRI genotype is described in the specification, and includes antibody based and nucleic acid based methods. (p. 12, line 3-p.17, line 23) In addition to descriptions in the specification, methods of identifying a FcαRI genotype of a cell are known in the art and encompass those methods detailed on pages 12-13 of the specification, such as DNA sequencing and PCR techniques, among others. Given the support found in the specification, Applicant submits that the step of "identifying a FcαRI

genotype of said cell" is disclosed such that one of skill in the art can practice it without undue experimentation.

A further step in a method of claim 1 is "quantifying IgA binding by said cell expressing said FcαRI genotype." Quantification of IgA binding is described in the specification. In particular, IgA binding may be by methods known in the art such as flow cytometry (p. 31, Example 22, and references 127-128), phagocytosis assay/flow cytometry (p. 29-30, Example 23) and other standard techniques such as "immunoprecipitation, SDS-PAGE, Western blotting and related methods" (p. 38) Given the support found in the specification, Applicant submits that the step of "quantifying IgA binding by said cell expressing said FcαRI genotype" is disclosed such that one of skill in the art can practice it without undue experimentation.

A further step of a method of claim 1 includes "comparing IgA binding by said cell and IgA binding by a second cell, said second cell expressing a second FcαRI genotype." It is well accepted case law that "[N]ot everything necessary to practice the invention need be disclosed. In fact, what is well known is best omitted. *In re Buchner*, 929 F.2d 660, 661, 18 USPQ2d 1331, 1332 (Fed. Cir. 1991). Techniques of comparing ligand binding by two cell types are well known in the art and it is submitted that one of skill in the art would know how to make such a comparison. Therefore Applicant believes this step of an inventive method is also fully enabled.

In summary, Applicant submits that the invention described in independent claim 1 and claims 2-12 which depend therefrom is disclosed such that one of skill in the art can practice it without undue experimentation and are therefore fully enabled. In view of these remarks it is respectfully requested that the rejection of claims 1-12 under 35 U.S.C. §112, first paragraph, be withdrawn.

Independent claim 13 and claims 14-21 which depend therefrom, describe a method for determining FcαRI alleles specific to an individual human, which Applicant believes to be disclosed such that one of skill in the art can practice it without undue experimentation.

A step in a method described by claim 13 includes "genotyping DNA encoding FcαRI for a polymorphism, said DNA being obtained from an individual human." As noted above, genotyping DNA for FcαRI polymorphisms is described in detail in the specification, in particular at p. 12, line 3 – p. 17, line 23. In addition, genotyping DNA encoding FcαRI for a polymorphism is described in several examples, for instance in Examples 3, 4 and 11. Applicant submits that claim 13 and claims 14-21 which depend therefrom are fully enabled. In view of these remarks it is respectfully requested that the rejection of claims 13-20 under 35 U.S.C. §112, first paragraph, be withdrawn.

The steps of a method of claim 26 include a step of "establishing a correlation between a FcαRI genotype and clinical outcome of said disease." Techniques for establishing a correlation between a genotype and clinical outcome of a disease are described in the specification, for example at p. 13, line 12 – p. 15, line 2. Specifically, it is noted that "[s]tatistical methods, illustratively including a 2x3 chi-square test is used to determine allele frequencies in disease and control groups. In this manner, it is possible to obtain statistically significant correlations between a given disease and FcαRI alleles and thereby a diagnostic as to disease susceptibility and clinical outcome." (p. 14, line 21 – p. 15, line 2) Further methods of correlation between a genotype and clinical outcome of a disease are known in the art and Applicant submits that given the description in the specification, one of skill in the art would be able to practice such techniques without undue experimentation.

Another step of a method of claim 26 is "genotyping a patient for FcαRI to yield a patient FcαRI genotype." As noted above, the identification of FcαRI genotype is described

in the specification as including antibody based and/or nucleic acid based methods. (p. 12, line 3 – p. 17, line 23) In addition to descriptions in the specification, methods of identifying a FcαRI genotype of a cell are known in the art and encompass those detailed on pages 12-13 of the specification, including DNA sequencing and PCR among others. Given the support found in the specification, Applicant submits that the step of "genotyping a patient for FcαRI to yield a patient FcαRI genotype" is disclosed such that one of skill in the art can practice it without undue experimentation.

A further step in a method of claim 26 is "comparing said FcαRI genotype with said patient genotype." "[N]ot everything necessary to practice the invention need be disclosed. In fact, what is well-known is best omitted. *In re Buchner*, 929 F.2d 660, 661, 18 USPQ2d 1331, 1332 (Fed. Cir. 1991). Techniques of comparing ligand binding by two cell types are well known in the art and it is submitted that one of skill in the art would know how to make such a comparison.

In summary, Applicant submits that the invention described in independent claim 26 and claims 27-30 which depend therefrom is disclosed such that one of skill in the art can practice it without undue experimentation and are therefore fully enabled. In view of these remarks it is respectfully requested that the rejection of claims 26-30 under 35 U.S.C. §112, first paragraph, be withdrawn.

Remarks Directed to Rejection under 35 U.S.C. §112, Second Paragraph

Claims 1-12, 26-30 and 35 stand rejected under 35 U.S.C. §112, second paragraph, as being indefinite for failing to recite a final process step that relates back to the preamble. (paper 16, p. 8-9) Independent claims 1 and 26 have been amended to clarify that a final process step relates back to the preamble. Claim 35 has been cancelled. In view of these remarks and the claim amendments, it is respectfully requested that the rejection of

independent claims 1 and 26, along with dependent claims 2-12 and 26-30 under 35 U.S.C. §112, second paragraph, be withdrawn.

Claims 31-33 are rejected under 35 U.S.C. §112, second paragraph, as indefinite for failing to particularly point out and distinctly claim the subject matter which Applicant regards as the invention. (paper 16, p. 9) Claims 31-33 have been cancelled.

Claims 13-21 are rejected under 35 U.S.C. §112, second paragraph, as indefinite because "the claims do not clarify the relationship between genotyping DNA and determining FcαRI alleles." (paper 16, p. 9) It is suggested that "determining the genotype of an individual doesn't necessarily lead one to the FcαRI alleles specific to an individual, it merely provides you with the genotype of that individual." (paper 16, p. 9-10)

In analyzing definiteness of claim language, the following are considered:

> (A) The content of the particular application disclosure;
>
> (B) The teachings of the prior art; and
>
> (C) The claim interpretation that would be given by one possessing the ordinary level of skill in the pertinent art at the time the invention was made. (MPEP 2173.02, 8th Edition)

In this case, terms used in the claim are defined in the specification as follows: "The term 'genotyping' as used herein as being the process of determining the allelic patterns of a human individual." (p. 18, lines 12-13); "The term 'allelic pattern' is intended to mean the identity of each of the two copies of a particular gene in a patient i.e., homozygosity or heterozygosity." (p. 18, lines 9-10). Thus, "genotyping DNA encoding FcαRI for a polymorphism, said DNA obtained from said individual human," clearly describes a method for determining FcαRI alleles specific to an individual human. Applicant submits that, analyzed in light of the disclosure and the plain language of the claim, the claim is definite.

Applicant requests that the rejection of claims 13-21 under 35 U.S.C. §112, second paragraph, be withdrawn.

Summary

Claims 1-21 and 26-30, 34 and 36-46 are the pending claims in this application. Claims 22-25, 31-33, and 35 have been cancelled. Each claim is believed to be in proper form and directed to allowable and patentable subject matter. Reconsideration and allowance of the claims is requested.

Respectfully submitted,

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Janice R. Kuehn